Dialysis Dialogue

North Dakota Department of Health
Division of Health Facilities

Summer 2002

Welcome to the second edition of *Dialysis Dialogue*, a newsletter published by the North Dakota Department of Health, Division of Health Facilities. *Dialysis Dialogue* is designed to help dialysis departments stay up-to-date on various issues. Please share with your dialysis staff.

Most Commonly Cited Deficiencies

Following is a breakdown of the most common deficiencies cited in the North Dakota ESRD program from Jan. 1, 2001, through Dec. 31, 2001.

- The most common deficiency cited in 2001 was V145, personnel policies and procedures. This requirement states that facility policies and procedures ensure a safe and sanitary environment for patients and personnel exists. This citation pertains not only to policy and procedure but to any practice that could adversely affect patients and personnel.
- The second most common deficiency cited was V186, patient long-term program and patient care plan. This requirement states that a copy of the current long-term program and patient care plan accompany the patient on interfacility transfers. Please be aware that an interfacility transfer includes the transfer to any facility with a different provider number from which a patient would receive services. This includes transfers from a satellite dialysis unit to the parent dialysis unit and also from a hospital-based dialysis unit to the acute care hospital within the same building structure.
- V191, patient long-term program, was the third most commonly cited deficiency. This requirement states that a copy of the patient's long-term program accompany the patient on interfacility transfers or is sent within one working day.
- Patient care plan, V197, was the fourth most commonly cited deficiency. This regulation states that if the patient is transferred to another facility, the care plan is sent with the patient or within one working day.
- The fifth most common deficiency cited was V281, emergency preparedness. This requirement states that there is available at all times on the premises a fully equipped emergency tray, including emergency drugs, medical supplies and equipment. This regulation also is cited when a facility's emergency tray contains expired medications.

Take a close look at your practices and identify if your facility is deficient in these areas; if so, take the appropriate actions to correct these areas prior to your next survey.

Hepatitis A Vaccine Recall

Merck & Company Inc. is voluntarily recalling specified lots of VAQTA (Hepatitis A vaccine, Inactivated) in prefilled syringes. Retests have revealed a decreased antigen content in some syringes below the established minimum specification. Patients who may have received doses from the indicated lots would have been vaccinated after May 29, 2001, with the adult formulation (50U/1 mL), and after Aug. 9, 1999, with the pediatric/adolescent formulation (25U/0.5 mL). More information is available at: www.fda.gov/medwatch/SAFETY/2001/safety01.htm#vaqta.

Counterfeit Epogen

Amgen Inc. recently became aware of the existence of counterfeit vials of Epogen in the United States. Amgen is warning that the fake products may pose a serious risk to patients because they do not contain proper doses of the drug. The counterfeit vials examined by Amgen to date contain a clear liquid that contains active ingredient. However, the concentration of active ingredient is about 20 times lower than expected for Epogen 40,000 U/ml vials. The effected vials are 10-pack boxes, lot number P002970 with an expiration date of July 2003. More information is available at: www.amgen.com/news/news02/release020506.html.

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It's always helpful to learn from your mistakes because then your mistakes seem worthwhile.

--Garry Marshall

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Audible Alarm Requirement

As a safeguard to ensure dialysis patients are exposed only to water that is considered safe, an alarm system needs to be in place.

- Is there an audible alarm to alert staff that product water may not be safe for use for dialysis?
- Is the alarm located where there will be staff to hear the alarm if it does sound?
- Is there a system in place to ensure that the alarm is functioning properly?

Heparin Sodium Recall

Wyeth Pharmaceuticals and ESI Lederle are voluntarily recalling all lots of Heparin Sodium Injection, USP (Porcine Derived) 1,000 units per mL, 1 mL DOSETTE ® Vial, 10 mL and 30 mL multiple-dose vials due to the presence of clear crystals containing an antioxidant compound from the vial rubber closures. More information is available at: www.fda.gov/medwatch/SAFETY/2002/safety02.htm#hepari.

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